



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
College Park, MD 20740

FEB - 4 2005

Mr. Dongning Wen
President
KNature Corporation
2489 173rd Place NE
Redmond, Washington 98052

Dear Mr. Wen:

This is in response to your letters of January 12, 2005 to the Food and Drug Administration (FDA) pursuant to 21 U.S.C. 343(r)(6) (section 403(r)(6) of the Federal Food, Drug, and Cosmetic Act (the Act)). Your letters state that the following statement, among others, will be made for the product Evening Primrose Oil: "[M]aintain blood pressure."

In the preamble to the January 6, 2000 final rule on structure/function claims (see 65 FR 1000 at 1018), FDA stated that claims about the maintenance of normal cholesterol levels did not necessarily constitute implied disease claims. We stated, however, that because "many people think of cholesterol solely in terms of the negative role of elevated cholesterol in heart disease," in order to avoid implying that the product prevents or treats heart disease, a cholesterol maintenance claim would have to clarify that the product is only for maintenance of cholesterol levels that are already within the normal range. The same principle applies to a claim about the control of blood pressure; that is, a claim that does not establish that the claim is about blood pressure that is already within normal limits implies that the product is intended to treat elevated blood pressure (hypertension), which is a disease. Therefore, because the claim you are making for this product represents that the product is intended to affect blood pressure but does not also include a statement about it being intended to affect blood pressure that is already in the normal range, it is an implied disease claim.

21 U.S.C. 343(r)(6) makes clear that a statement included in labeling under the authority of that section may not claim to diagnose, mitigate, treat, cure, or prevent a specific disease or class of diseases. The statement that you are making for this product suggests that it is intended to treat, prevent, or mitigate a disease. This claim does not meet the requirements of 21 U.S.C. 343(r)(6). This claim suggests that this product is intended for use as a drug within the meaning of 21 U.S.C. 321(g)(1)(B), and that it is subject to regulation under the drug provisions of the Act. If you intend to make claims of this nature, you should contact FDA's Center for Drug Evaluation and Research (CDER), Office of Compliance, HFD-310, Montrose Metro II, 11919 Rockville Pike, Rockville, Maryland 20855.

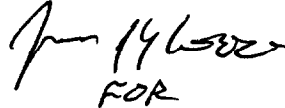
978-0163

LET 807

Page 2 - Mr. Dongning Wen

Please contact us if we may be of further assistance.

Sincerely yours,



Susan J. Walker, M.D.
Director
Division of Dietary Supplement Programs
Office of Nutritional Products, Labeling
and Dietary Supplements
Center for Food Safety
and Applied Nutrition

Copies:

FDA, Center for Drug Evaluation and Research, Office of Compliance, HFD-310

FDA, Office of the Associate Commissioner for Regulatory Affairs, Office of
Enforcement, HFC-200

FDA, Seattle District Office, Office of Compliance, HFR-PA340

KNATURE CORPORATION

2489 173rd Pl. NE
Redmond, WA 98052

Tel: (425) 649-2075; Email: knaturecorp@msn.com

Office of Special Nutritional (HFS-450)
Center for Food Safety and Applied Nutrition
Food and Drug Administration
200 C Street SW
Washington, DC 20204

Dec'd
JAN 21 2005

Jan 12th, 2005

Notification letter for Statement on Dietary Supplement

Dear FDA officers:

I am the president of Knature Corporation, who is, among other things, a manufacturer and distributor of dietary supplements, mostly herbal products in the United States. I am writing as per Code of Federal Regulations, Volume 21, Part 101.93, to notify you that we have included a statement on the label or in the labeling of one of our products. The following are the information required in this notification letter:

1. Statement of Purpose:

This is a letter to provide notification of a statement of nutritional support, including the exact wording that appears on the label and labeling for a dietary supplement.

2. Vendor Information:

Name, address, telephone and fax numbers of the manufacturer and distributor for mailing and other communication purposes, are as follows:

Knature Corporation

2489 173rd Pl. NE
Redmond, WA 98052

Tel: (425)649-2075,

90744

6. Intended Use:

This product is intended to be used by person over the age of 14.

Dosage: As a dietary supplement, take 1-2 soft gel, twice daily after meal.

Warning: Keep out of reach of children. If you are pregnant or lactating, or taking a prescription medication, consult a physician before using this product. To be kept in a cool and dry place.

7. Statement of Affirmation:

We, as a distributor of the above mentioned product, affirm that we have substantiation that the structure/function statement (as shown in No. 4 above) made under 403(6)(r) of the Federal Food, Drug and Cosmetic Act is truthful, not misleading, and scientifically valid and that the product does not present a significant or unreasonable risk of illness or injury under the conditions of use recommended or suggested in the label or labeling.

8. Disclaimer:

At the end of each structure/function statement, there is an asterisk that refers to another asterisk placed adjacent to another statement called disclaimer. The disclaimer is placed at the bottom of the same panel or, in adjacent with the structure/function statement, The disclaimer reads:

**The statement has not been evaluated by the Food and Drug Administration.
This product is not intended to diagnose, treat, cure, or prevent any disease.**

Should there be any question or comment, please contact the Vendor through the information in No. 2 above.

Sincerely,



Dongning Wen
President

Enclosure

Evening Primrose Oil

**Source of GLA
Hexane Free
Naturally Cold Pressed
Dietary Supplement**

500 mg, 180 softgels

Evening Primrose Oil is a natural source of Omega-6 fatty acids with a guaranteed level of Gamma Linolenic Acid (GLA).

EPO helps to promote women's well-being. It can provide nutritional support for woman with PMS, Menstruation, Menopause.*

EPO helps regulate fat metabolism, inflammatory response, hormones, as well as cardiovascular, immune and central nervous systems.*

EPO also maintain blood pressure, sustain healthy skin and support joints.*

Vitamin E is added to enhance long term freshness and ensure a more stable product without artificial preservatives.*

* These statements have not been evaluated by the Food and Drug Administration. This product is not intended to diagnose, treat, cure, or prevent any disease.

Directions: 1-2 softgel, twice daily after meal.

Warning:

Not recommended for male; or female under the age of 15. Consult your physician if you are on any type of medication. Keep out of reach of children.

Distributed by:

Knature Corporation, Redmond, WA98052
Tel: (425)649-2075.

Manufactured by: Sheng Sheng Pharmaceuticals Ltd., Co., China

Expire Date: Dec, 2009

Nutrition Facts

